SECTION NINE

FINAL REGULATORY FLEXIBILITY ANALYSIS

9.1 INTRODUCTION

This section examines the projected effects of the costs from incremental pollution control on small entities as required by the Regulatory Flexibility Act (RFA, 5 U.S.C. 601 et seq., Public Law 96-354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). EPA is not bound by the requirements of SBREFA because this amendment became effective after the Pharmaceutical Industry Effluent Guidelines were proposed. Nevertheless, EPA has followed guidance on the analyses recommended under the RFA as amended. This section determines impacts on small entities resulting from the Final Pharmaceutical Industry Effluent Guidelines, separately from and together with, the MACT standards rule.

The RFA acknowledges that small entities have limited resources and makes the regulating federal agency responsible for avoiding burdening such entities unnecessarily. Pursuant to the RFA, EPA has prepared a final regulatory flexibility analysis (FRFA).[1] Section 9.2 reviews the steps suggested in Agency guidance materials to determine whether a regulatory flexibility analysis is required and how to identify significant impacts on small businesses. Section 9.3 responds to the regulatory flexibility analysis components required for a final rule by Section 604 of the RFA. Section 9.4 is a detailed description of the small business economic analysis performed for the proposed regulation.

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[1] The preparation of an FRFA for a final rule does not legally foreclose certifying no significant impact for the final rule; see U.S. EPA, 1997. *Interim Guidance for Implementing the Small Business Regulatory Enforcement Fairness Act and Related Provisions of the Regulatory Flexibility Act.* February 5.

9.2 INITIAL ASSESSMENT

The following passage lists the initial assessment steps suggested in current EPA guidance.[2] The steps are posed as a series of questions and answers:

- Is the Rule Subject to Notice-and-Comment Rulemaking Requirements?

  The Effluent Limitations Guidelines and Standards for the Pharmaceutical Industry is subject to notice-and-comment rulemaking requirements.

- Profile of Affected Entities

  EPA prepared a profile of the regulated universe of entities; see Section Three and Section Three of the EIA for the proposal (the universe and profile has not changed significantly since proposal).

- Will the Rule Affect Small Entities?

  Yes, EPA has identified a maximum of 145 small entities subject to the rule.

- Will the Rule Have an Adverse Economic Impact on Small Entities?

  EPA has determined that some small entities might incur costs for incremental pollution control as a result of the rule. EPA examines the impacts of these additional costs in Section 9.4, as well as in this initial assessment section.

EPA can perform an initial assessment of the potential for a rule to result in adverse impacts on small entities. This initial assessment can indicate whether the rule requires a regulatory flexibility analysis to be performed. EPA's guidance for performing this initial assessment[3] suggests the use of a revenue test (annual compliance costs as a percentage of annual revenues) to determine whether a rule will have a significant impact on a substantial number of small entities. If the number or percentage of firms exceeding certain benchmarks is low (for example, if fewer than 100 firms incur costs that are greater than 1 percent of annual revenues and if fewer than 100 firms incur costs that exceed 3 percent of annual revenues), the rule is considered to meet qualifications allowing the EPA Administrator to certify the rule as having no significant

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[2] U.S. EPA, 1992. *EPA Guidelines for Implementing the Regulatory Flexibility Act.* U.S. Environmental Protection Agency, Office of Policy, Planning, and Evaluation, April; and U.S. EPA, 1997. *Op. cit.*

[3] U.S. EPA, 1997, *Op. cit.*

impact on a substantial number of small entities. As Table 9-1 shows, only 4 small firms or 3.2 percent of all small firms that could be analyzed will incur annual compliance costs that are greater than 1 percent of annual revenues and no firms will incur costs exceeding 3 percent of annual revenues. Even when MACT Baseline 3 costs are added in, only 6 firms (4.8 percent) will incur annual compliance costs that are greater than 1 percent of revenues and 1 firm (0.8 percent) will incur annual costs greater than 3 percent. This firm, however, incurs only the costs of the MACT standards rule (costs for the Final Pharmaceutical Industry Effluent Guidelines are zero), and therefore is not considered to be an affected firm in this RFA. The Final Pharmaceutical Industry Effluent Guidelines are thus considered a Category 1 rule. Category 1 rules may be certified as having no significant impact on a substantial number of small entities without performing a FRFA. To further support this finding, however, EPA follows with a FRFA in Sections 9.3 and 9.4, below.

9.3 REGULATORY FLEXIBILITY ANALYSIS COMPONENTS

Section 604 of the RFA requires that an FRFA must:

- state the need for and objectives of the rule.
- summarize the significant issues raised by public comments on the initial regulatory flexibility analysis (IRFA) and the Agency's assessment of those issues, and describe any changes in the rule resulting from public comments.
- describe the steps the Agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant regulatory alternatives to the rule considered by the Agency which affect the impact on small entities was rejected.
- describe/estimate the number of small entities to which the rule will apply or explain why no such estimate is available.
- describe the projected reporting recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirements of the rule.

The following sections address these issues.

Table 9-1

SBREFA Revenue Test Analysis

Impact Category Costs/Revenue	Final Pharmaceutical Industry Effluent Guidelines		Effluent Guidelines plus MACT Standards Rule	
	Number of Small Firms *	Percentage of All Small Firms	Number of Small Firms	Percentage of All Small Firms
> 1 Percent	4	3.2%	6	4.8%
> 3 Percent	0	0.0%	1	0.8%

* Small firms are defined as those with less than 750 employees.
Note: Three small firms were left out of the analysis due to insufficient revenue data.

9.3.1 Need for and Objectives of the Rule

The rule is being proposed under the authority of Sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act, 33 U.S.C. Sections 1311, 1314, 1316, 1317, 1318, and 1361. Under these sections, EPA is setting effluent guidelines and standards for the control of discharge of pollutants for the Pharmaceutical Industry Point Source Category. The regulations also are being proposed pursuant to a Consent Decree entered in NRDC et al. v. Reilly (D.D.C. No. 89-2980, January 31, 1992), and are consistent with EPA's latest Effluent Guidelines Plan under Section 304(m) of the CWA (see 61 FR 52582, October 7, 1996).

The objective of the CWA is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." To assist in achieving this objective, EPA issues effluent limitations guidelines; pretreatment standards, and new source performance standards for industrial dischargers. Sections 301(b)(1) and 304(b)(1) authorize EPA to issue BPT effluent limitations guidelines; Section 304(b)(4) authorizes EPA to issue BCT guidelines for conventional pollutants; Sections 301(b)(2)(E) and 304(b)(2) authorize EPA to issue BAT guidelines to control nonconventional and toxic pollutants; Section 306 authorizes EPA to issue NSPS for all pollutants; and Sections 304(g) and 307(b) authorize EPA to issue PSES and PSNS for all pollutants.

9.3.2 Significant Issues Raised by Public Comments on the IFRA

Three issues were raised in public comments on the IFRA. One commenter suggested that "adding pilot-scale operations to the [rule] will leave small biotech firms economically disadvantaged." EPA, however, will not revise the scope of applicability for the rule to include research (Subcategory E) facilities. The same commenter states that "EPA has assumed that capital costs for control equipment will be offset by rolling costs back to consumers purchasing drugs currently on the market....[Start up biotech companies do not have any drugs on the market to offset these costs...." EPA, in fact, did not assume that costs could be passed on to consumers, and all impacts identified in this EA, other than those on consumers, are estimated assuming that costs cannot be passed through. Another commenter states that "[impact of the regulation

biases disproportionately on small firms." EPA disagrees. The impacts of the rule are minimal and, as discussed below, are not disproportionate. See EPA's comment response document.[4]

9.3.3 Steps the Agency Has Taken To Minimize Significant Economic Impact on Small Entities

The Agency has taken no steps to minimize significant economic impacts on small entities, because very few small entities are expected to experience significant economic impacts. The only alternatives that are less costly to small entities than those selected for the final rule are no-action alternatives, which are, for the most part, not considered to meet the objectives of the Clean Water Act. Although a no-action alternative was chosen for one subcategory (BAT for BD directs), this decision was made neither on the basis of economic achievability nor on the basis of minimizing significant economic impacts on small entities.

9.3.4 Describe/Estimate the Number of Small Entities To Which the Rule Will Apply

EPA estimates that a maximum of 145 out of 190 (76 percent) pharmaceutical firms subject to the rule might be classified as small under SBA definitions. Small firms are defined in 13CFR Part 121 either by their employment size or by their revenues. As discussed in Sections Two and Three of this report, the major SIC categories affected by the Final Pharmaceutical Industry Effluent Guidelines are SICs 2833, 2834, 2835, and 2836. In SIC 2833 and 2834, small firms are defined as those employing 750 or fewer persons; in SIC 2835 and 2836, those employing 500 or fewer persons are defined as small. For simplicity, and as done in the Initial Regulatory Flexibility Analysis (IRFA) at proposal, this FRFA designates all pharmaceutical firms as small if they employ fewer than 750 persons. These firms and their facilities were profiled in Section Three of this EA.

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[4] U.S. EPA, 1998. *Comment Response Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*.

9.3.5 Describe Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

Under current law, before this rule, as well as after implementation of this rule, all affected firms are subject to monitoring and permitting requirements.

9.4 IMPACTS OF THE FINAL RULE ON SMALL ENTITIES

EPA has selected facility closures and firm failures as identifying measures of significant impact in this FRFA. As discussed in Sections Five and Six of this EA, one facility owned by a multifacility firm will close (although only if MACT standards costs are included), one single-facility firm will fail and close, two single-facility firms will fail but will probably not close (i.e., they will lose their financial independence), and one multifacility firm will fail or must sell (but not close) one or more of its facilities. All of the firms associated with these impacts are small firms. Given that 76 percent of all affected firms are small, this result is not disproportionate. If exact proportionality of impacts were to have occurred, we could expect out of five significantly affected firms that four would have been small. The difference between four significantly affected small firms out of five total affected firms (large or small) and five significantly affected small firms out of five total affected firms is minimal.